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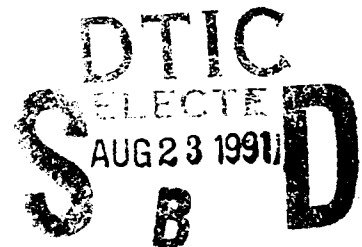


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TESTING AND EVALUATION OF THE CATALYST RESEARCH MINIOX III OXYGEN MONITOR

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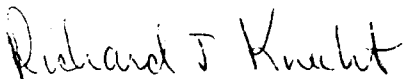
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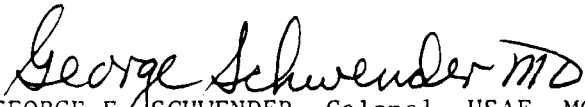
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13. ABSTRACT (Maximum 200 words) The Military Airlift Command (MAC) directs and controls aeromedical evacuation missions for the United States Air Force (USAF) and most of the Department of Defense (DOD). There is often a need to monitor and control the percentage of therapeutic oxygen being administered to patients. The Catalyst Research MiniOX III oxygen monitor was selected by MAC as its primary oxygen monitoring device. The Aeromedical Research Function tested and evaluated the MiniOX III, and found it to be a safe and reliable device and acceptable for worldwide aeromedical evacuation use.				
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TESTING AND EVALUATION OF THE CATALYST RESEARCH MINIOX III OXYGEN MONITOR

BACKGROUND

The United States Air Force (USAF) Military Airlift Command (MAC) directs and controls aeromedical evacuation missions for the USAF and most of the Department of Defense (DOD). There is, at times, a critical need to monitor the concentration of therapeutic oxygen being administered to patients during aeromedical evacuation, particularly infants. The Biomarine Model 400 Oxygen Analyzer/Controller has been the only device approved for this purpose. However, the Biomarine is technologically obsolete and no longer manufactured. MAC has selected the MiniOX III oxygen monitor as the replacement for aeromedical evacuation use.

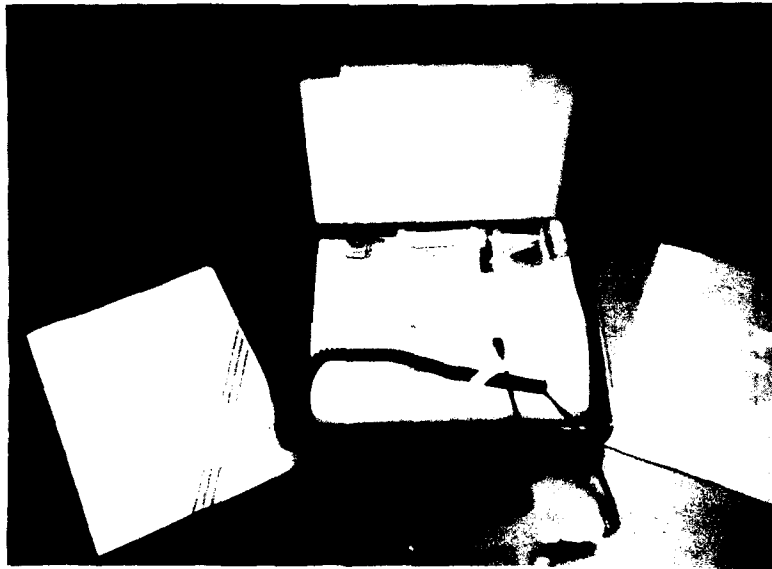


Figure 1. The Catalyst Research MiniOX III Oxygen Monitor.

DESCRIPTION

The MiniOX III (Fig. 1), manufactured by Catalyst Research (a Division of Mine Safety Appliances Company), is designed to provide continuous oxygen monitoring in a wide variety of medical applications such as respiratory therapy, anesthesiology, neonatal care, emergency transports, and oxygen therapy.

The instrument is microprocessor controlled and monitors oxygen concentrations in the full 0 to 100% range. It uses a galvanic oxygen sensor (Catalyst Research part number 406931). Features include high/low audible and visual alarms, easy to read digital displays, touch sensitive keypad, low battery alarm, and sensor malfunction indicator. The microprocessor makes the MiniOX III easy to calibrate and simple to use.

METHODS

The Aeromedical Research Function (ARF) develops test procedures that cover safety and human factors issues regarding the equipment to be tested. A performance check is developed that verifies proper functioning of the equipment under various conditions.

The device is then subjected to various "referee tests" to check its performance under various anticipated operational conditions. The following tests generally involve a repetition of the performance check under the specified conditions:

1. Electromagnetic Interference (EMI)
2. Vibration
3. Environmental, which encompasses:
 - a. Humidity
 - b. Hot Operation
 - c. Cold Operation
 - d. Hot Storage
 - e. Cold Storage
4. Altitude, which encompasses:
 - a. Hypobaric chamber testing
 - b. Rapid decompression testing
5. Airborne Feasibility

Each test also includes any special measurements or procedures necessary, due to the peculiarities of the testing conditions.

To verify the MiniOX's displayed oxygen concentrations and response time, we constructed a flow column or test setup which comprised the following components:

1. MiniOX III tee-adaptor p/n 473021
2. Bird Bifurcation Connector p/n 9991003
3. Bird Connector p/n 9991220
4. Bird Connector p/n 9992187
5. Bird Connector p/n 2455
6. Medical Grade PVC Tubing 0.95 cm (3/8 in.) i.d. x 114.30 cm (45 in.)
7. Ohio Pressure Compensated Oxygen Flowmeter
8. Bird Oxygen Blender Model 3300
9. Low Pressure Medical Grade Oxygen Hose 4.57 m (15 ft)
10. Low Pressure Compressed Air Hose 4.57 m (15 ft)
11. Bird Oxygen Regulator Model 1227
12. Veriflo Air Regulator Model 747346PG
13. High Pressure Medical Grade Oxygen Cylinder "H" Size
14. High Pressure Compressed Air Cylinder "H" Size

The test setup held the MiniOX oxygen sensor, installed in the monitor's tee-adaptor. We used a Perkin Elmer Model 1100 Medical Gas Analyzer (MGA) as a reference to compare to the oxygen concentration readings indicated by the MiniOX.

The MGA gas sampling line was placed in the test setup through the distal end outlet opening, so that the tip was in close proximity (1 - 2 cm) to the MiniOX sensor. A Grant Squirrel Meter/Logger Model 1201 was used to record the in-line humidity and temperature. The attached humidity/temperature probe, Vaisala Model HMP 31 UTA, was placed inline with the test setup through the Bird Bifurcation Connector (Fig. 2).

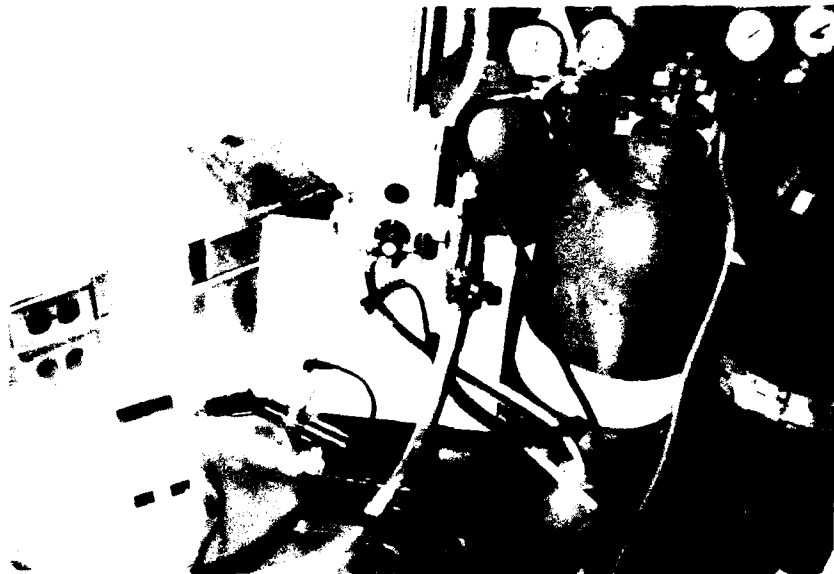


Figure 2. MiniOX III test setup.

Performance Check

The oxygen and compressed air were supplied to the blender via the regulators at 50 psi. The blended oxygen, via the flowmeter, was maintained at 4 lpm. During a performance check, by modulating the blender, we varied the oxygen concentrations from 21% (room air), to 50%, to 100%, and then back to 21%. During each change in concentration we recorded the MiniOX oxygen concentration reading every 10 s during the first minute, and every minute thereafter for at least 4 additional minutes. Also, the sensor response time was measured and recorded. With the low alarm set at 50%, and the sensor exposed to 100% oxygen, the sensor was abruptly removed and exposed to 21% room air. The response time was the time required for the display to fall from 100 to 50%. This also enabled us to check the alarm function with each performance check. For comparison, the MGA readings were also recorded.

Baseline Performance Assessment

The primary purpose of the Baseline Performance Assessment (BPA) is to quantitatively measure and document the oxygen monitor's performance under ambient room conditions before any further reference testing. The BPA will be used as a reference to measure subsequent performance, to verify selected manufacturer and contract specifications, and to ensure safe operation before testing. Procedures used were derived from AFR 160-3, Electrical Safety in Medical Treatment Facilities (2), the manufacturer's operating manual (1), and our staff's experience with similar devices. The following 6 paragraphs are specific measurements taken during the BPA:

1. **Displayed Oxygen Concentration Accuracy:** Accuracy was verified against the MGA, starting with concentrations of 21% increasing up to 100%, in increments of 10%.
2. **Displayed Oxygen Concentration Accuracy During 24 h of Operation:** Accuracy was verified by operating the unit for a 24-h period and making numerous performance checks (21%, 50%, and 100% oxygen) throughout the 24 h.
3. **Electrical Safety:** The MiniOX has no exposed metal surfaces and receives its power from an internal 9 v alkaline battery. Therefore, leakage current and ground resistance measurements were unnecessary.
4. **Alarms:**
 - a. **High and Low Oxygen Concentration:** Each alarm, high and low, was verified by slowly increasing or decreasing the oxygen concentration above or below the alarm set point. Alarm activation was checked at every 10% concentration within its operating range.
 - b. **Low Battery:** Verified by removing the battery and using an adjustable direct current (DC) power supply in its place.
5. **Response Time:** This response time is the time required for the display to reflect a change in percent from 100% oxygen to 50%, after the sensor is removed from 100% and exposed to room air.
6. **Calibration:** Two methods, described next, were assessed.
 - a. **High Point Calibration:** According to the operating manual this is the preferred method of calibration since it validates the linearity of the sensor. The sensor was placed in the test setup through the tee-adaptor port. With the blender set at 100%, and verified by the MGA, 5 min were allowed for the MiniOX display to stabilize. At that point, following the operating manual, the MiniOX was calibrated to read the same as the MGA, between 99 and 100%. Following this calibration, the sensor was removed from the test setup and exposed to room air. The MiniOX display was observed to ensure the reading dropped to 21% ($\pm 2\%$ of full-scale), within 5 min.
 - b. **Low Point Calibration:** The sensor was exposed to room air for 5 min. Then calibration was performed according to the operating manual.

Electromagnetic Interference

The purpose of this test was to verify compliance with MIL-STD-461C, Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference, Category A1e (3).

1. **Radiated Emissions (RE-02):** This test measures radiated emissions generated by the oxygen monitor. Excessive emissions could interfere with aircraft navigation and communication equipment. The oxygen monitor was tested while operating on 9 VDC.

the only power source available. The monitor was turned on, with the light-emitting diode (LED) display indicating the percentage of oxygen of ambient air, about 21%.

2. Radiated Susceptibility (RS-02): This test determines whether the ambient electromagnetic fields (noise) encountered in flight interferes with the operation of the oxygen monitor. The monitor was exposed to the electromagnetic induction fields described in the USAFSAM Test and Evaluation Planning Guide for Aeromedical Equipment (4). During exposure, the monitor was operated on 9 VDC battery power while monitoring ambient air oxygen percentage.

Vibration

Using MIL-STD-810D (5) as a guide, these tests consist of random and sinusoidal X, Y, and Z curves, to test the monitor's construction, durability, and performance, and the integrity of the mounting devices during worst case vibration scenarios. The Unholtz-Dickey Vibration Control Console and Vibration Table at USAFSAM Engineering and Maintenance Services Branch (TSNB) was used for the tests. Using the mounting device provided by the manufacturer, the MiniOX was secured to a pole of a standard North Atlantic Treaty Organization (NATO) litter, which was bolted to a 0.63 cm (1/4 in.) metal plate. This setup was secured to the vibration table. The console and table were operated by technicians from TSNB, who programmed the control console for five 15-min cycles, totaling 75 min at each axis for the sinusoidal testing; and 30 min at each axis for the random testing. Before and following the tests, a visual examination and performance check was conducted. During the tests the unit was under close observation, and performance checks were conducted every 15 min.

Environmental

These tests measured the MiniOX's performance under varying temperature and humidity conditions encountered during in-flight use and ground level storage. The Standard Environmental Systems Model TAH/15 environmental chamber was used; operated and controlled by technicians from TSNB. The MiniOX, with the sensor installed near 1 end of the test setup, was placed in the center of the environmental chamber. The other end of the test setup was routed through a port in the chamber wall, which was subsequently sealed with putty. This end, including the gas sources and the MGA, was outside the chamber.

The Grant 1201 Squirrel Meter/Logger was used to record temperature and relative humidity, both in the test setup and inside the environmental chamber. A performance check was conducted before and after each test. The following paragraphs describe the conditions of each environmental test performed:

1. Humidity: The environmental chamber conditions were set at 95% relative humidity at 29.4 °C (85 °F). The MiniOX was placed in the chamber for 4 h. Controlling the gas flow from the blender outside the chamber, a performance check was conducted every 30 min during the 4 h. Through a viewing window in the chamber door, the research technicians were able to observe the MiniOX percentage readings.

2. Hot Operation: The environmental chamber was set at 48.8 °C. (120 °F). The MiniOX was placed in the chamber for 2 h. Controlling the gas flow from the blender outside the chamber, a performance check was conducted every 15 min. Through a viewing window in the chamber door, the research technicians were able to observe the MiniOX percentage readings.

3. Cold Operation: The environmental chamber was set at 4.4 °C (40 °F). The MiniOX was placed in the chamber for 2 h. Controlling the gas flow from the blender outside the chamber, a performance check was conducted every 15 min. Through a viewing window in the chamber door, the research technicians were able to observe the MiniOX percentage readings.

4. Hot Storage: The environmental chamber was set at 48.8 °C (120 °F). The MiniOX was placed in the chamber for 8 h. Performance tests and visual examinations were conducted before and after the chamber storage, under ambient conditions, with room air at 21.1 °C (70 °F).

5. Cold Storage: The environmental chamber was set at -17.8 °C (0 °F). The MiniOX was placed in the chamber for 8 h. Performance tests and visual examinations were conducted before and after the chamber storage under ambient conditions, with room air at 22.2 °C (72 °F).

Altitude

Since this instrument is significantly affected by changes in altitude, a brief review of altitude physiology follows:

1. Respiratory Physiology. A clear understanding of the relationship of percentage vs. partial pressure is essential to understanding the operation and use of the MiniOX III. Oxygen gas exchange occurs at the alveolar level, through diffusion powered by a difference in partial pressure between alveolar oxygen (103 mmHg at sea level, breathing room air) and oxygen in the venous blood arriving at the pulmonary system (typically 40 mmHg, healthy adult). Some individuals in the medical community have been accustomed to prescribing oxygen and other medical gases in terms of percentage, rather than partial pressure. In fixed medical treatment facilities, this method of prescription works very well. However, in the aeromedical transport environment it presents a problem. Each time the aircraft changes altitude, a change in total pressure, and a corresponding change in the partial pressure of oxygen, occur. The percent oxygen is constant in the air at all altitudes, while the partial pressure changes in direct proportion to the total pressure (which is a function of altitude). This relationship is expressed in the following formula:

$$\frac{\text{Partial Pressure of Oxygen (PP)}}{\text{Atmospheric Pressure (AP)}} = \text{Percent (\%) Oxygen} \quad (1)$$

$$\text{or: } \% \times \text{AP} = \text{PP}$$

Using this formula, we can see that 21% oxygen at 3,048 m (10,000 ft) ($21\% \times 523 \text{ mmHg} = 109 \text{ mmHg}$) is a lower partial pressure (i.e., a smaller mass or amount of oxygen in the same volume) than that obtained at sea level ($21\% \times 760 = 160 \text{ mmHg}$). Remember, the clinically relevant parameter which is physiologically significant during transport, to meet patient oxygen requirements, is partial pressure not percentage.

2. Analyzer Theory of Operation. The following is a synopsis of the basic operation of both the MiniOX III and Perkin Elmer Model 1100 Medical Gas Analyzer.

a. MiniOX III. The MiniOX sensor actually responds to changes in the partial pressure of oxygen. However, the sensor converts the partial pressure signals to percent oxygen concentration for the altitude where it was calibrated, using the previous formula, with "AP" representing the atmospheric pressure at the time of the last calibration. After calibrating the MiniOX at a given atmospheric pressure, all subsequent readings are based on the current partial pressure of oxygen but are related back to AP at time of calibration, regardless of the actual atmospheric pressure at the time of the measurement. This calibration works very well in a fixed facility, but presents significant problems in an environment where atmospheric pressure changes. The problems are reviewed in the results section of this report.

b. Medical Gas Analyzer. Our reference oxygen analyzer, which the MiniOX is compared to, is the Perkin Elmer Model 1100 Medical Gas Analyzer (MGA). The analyzer operating principle (magnetic sector mass spectrometry) is much different from the MiniOX and its concentration reading is insignificantly affected by changes in partial pressure between sea level and 10,000 ft.

3. Testing. Extensive altitude testing was conducted to verify the relationship between the MiniOX display and the actual partial pressure of oxygen. Each altitude run normally involved measurements made at altitudes of 2K, 4K, 6K, 8K and 10K ft above sea level; testing oxygen concentrations of 21, 50 and 100% at each altitude (Fig. 3).

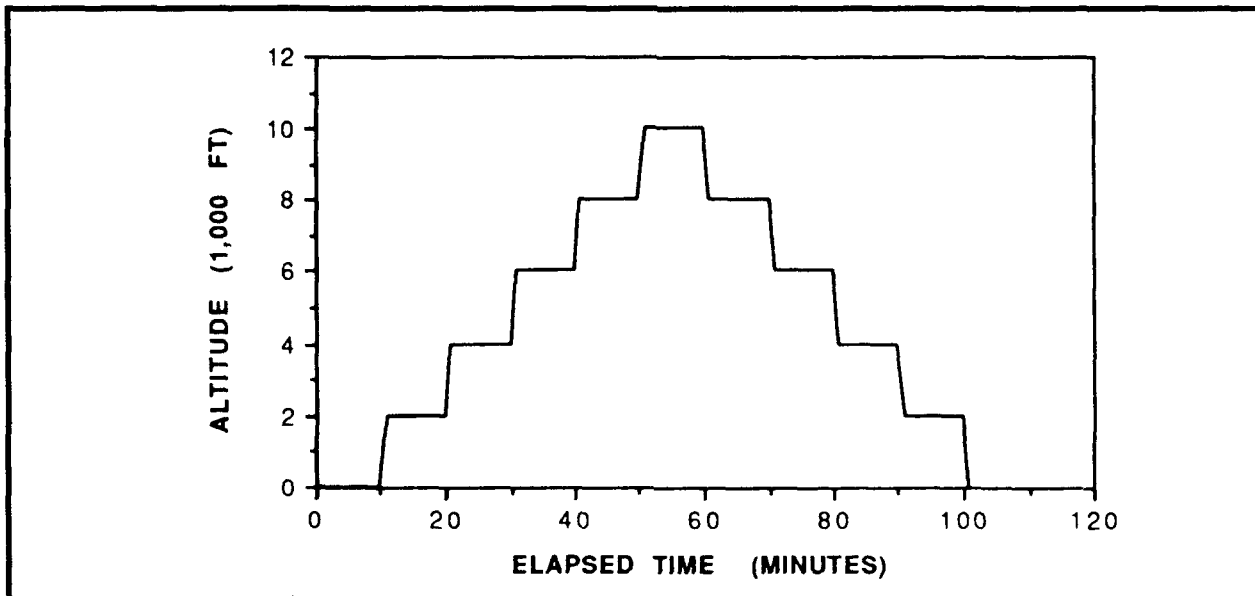


Figure 3. Typical altitude testing profile.

These tests were conducted with assistance and monitoring by the personnel from USAFSAM Crew Technology Division Chamber Operations (VNSO). During these tests, the MiniOX and the test setup, including the oxygen and air sources, were located inside the altitude chamber. The MGA was located outside the chamber, but visible through a viewing window. The sampling line from the MGA to the test setup was routed through sealed port holes in the chamber wall. Using the MGA as a standard, the different concentrations of oxygen were delivered through the test setup, as described in the performance check paragraph. The readings of both the MGA and the MiniOX were compared and recorded. Specific tests, conducted at each altitude level, included:

- a. Measurement of the MiniOX's response time, following changes in delivered oxygen concentration.
- b. The MiniOX's ability to be properly calibrated.
- c. The reliability of the alarm functions.
- d. The reliability of the sensors.
- e. Operating the MiniOX without the test setup, with the sensor placed inside an oxygen-enriched Ohio Transport Incubator. These testing sessions involved removing the sensor from the incubator at each altitude change, for the purpose of calibration to room air at that atmospheric pressure.
- f. Calibrating the MiniOX at altitude, and using a conversion chart to adjust the amount of oxygen needed to provide the same partial pressure of oxygen as that needed at ground level.
- g. The MiniOX's response to changes in partial pressure of oxygen, when not calibrated at altitude. Also the ability of the MiniOX to display a corresponding changed percentage reading, directly proportional to the change in the partial pressure of oxygen. The ability of the MiniOX to accurately reflect the imposed changes in partial pressure of oxygen, when the oxygen concentration is modulated using the test setup or other means.
- h. Exposing the MiniOX to a series of rapid decompression tests; with the MiniOX operating at an altitude of 2,438 m (8,000 ft) with subsequent changes of altitude to 12,192 m (40,000 ft) over periods of 60, 7, and 1 s.

Airborne Feasibility

Two qualified Aeromedical Research technicians performed this phase of testing on actual aeromedical evacuation missions, using the C-9A and C-141B aircraft. On the C-9A, testing was conducted on a series of flights totalling about 4 h, with a ceiling altitude of 7,620 m (25,000 ft) and 1,829 m (6,000 ft) equivalent cabin altitude. Itinerary on the first mission was from Kelly AFB TX to Andrews AFB MD, with an enroute stop at Keesler AFB MS. On the second mission, the itinerary was from Scott AFB IL to Kelly AFB TX. On the C-141B, testing was conducted on a series of

flights totaling about 14 h, with a ceiling altitude of 12,192 m (40,000 ft) and 1,829 m (6,000 ft) equivalent cabin altitude. Itinerary on the first mission was from Andrews AFB MD to Roosevelt Roads NAS, Puerto Rico, with an enroute stop at Guantanamo Bay, Cuba. Itinerary on the second mission was a reversal of the first. The purpose of the testing was to evaluate the MiniOX's ability to function effectively while in an environment where it would be subject to the highest altitude, longest flight time, most vibration, and most environmental extremes; hence the C-141 was chosen for most of the testing.

With a NATO litter as a testing station, the same test setup and test equipment setup described earlier were used; with the following exceptions:

1. The oxygen source was from the aircraft liquid oxygen converter system.
2. Due to its extreme weight and sensitivity, it was not feasible to transport the MGA. Therefore, verification of the MiniOX gas concentration display was not possible.

The MiniOX was operated according to manufacturer's instructions, using the standard test setup, and also by placing the sensor in an oxygen-enriched infant chamber of an Ohio Infant Transport Incubator. The relative humidity and temperature of the ambient air, air inside the incubator, and air inside the test setup were monitored using the Squirrel Meter/Logger. Standard performance checks were accomplished using the test setup. Also tested was the time taken for the MiniOX reading to stabilize following sensor removal from the oxygen-enriched incubator to ambient air, and vice-versa. Calibration procedures were checked, using room air and 100% oxygen via the test setup. Also evaluated were the visibility of visual alarms, audibility of the audible alarms, and locations aboard the aircraft at which the MiniOX could be satisfactorily mounted. Use while enplaning and deplaning was evaluated, as well as crew acceptance. Due to the small size of the MiniOX III, form and fit evaluation on other aeromedical airframes, including the C-130, C-12, C-21, UH-1, and UH-60, was not deemed necessary.

RESULTS

Baseline Performance Assessment

1. Displayed Oxygen Concentration Accuracy: All measurements were within the contract specifications of 3%. The greatest inaccuracy was 1.9% at 100% oxygen.
2. Displayed Oxygen Concentration Accuracy During 24-h of Operation: Displayed oxygen concentration remained within 3% throughout the 24-h period.
3. Electrical Safety: Leakage current and ground resistance measurements were unnecessary. No discrepancies were noted during visual examination.
4. Alarms:

a. High/Low Oxygen Concentration: Activated within 2% of full scale of set point.

b. Low Battery: The low battery alarms activated as stated by the manufacturer. "Lo Batt" activation with a beep sound every 30 s occurred at 7 v and the "Off Lo Batt" alarm with a continuous beep occurred at 6.7 VDC. Accuracy of the measured oxygen was also measured during this test and remained within 3%.

5. Response Time: The response time met the manufacturer's specifications. No response time is specified in the purchase contract.

6. Calibration:

a. High Point Calibration: Calibration was easily and accurately performed, using this method. As stated by the manufacturer, this method is indeed preferable to Low Point calibration. We recommended following High Point Calibration, the sensor should be removed from the tee-adaptor and exposed to room air. The MiniOX display should be observed to ensure that the reading drops 21% ($\pm 2\%$ of full-scale) within 5 min. If this does not occur, the calibration should be repeated. If this again does not occur, the sensor should be replaced. Do not recalibrate to make the display show exactly 21%. A variance of $\pm 2\%$ of full-scale is acceptable.

b. Low Point Calibration: This method is acceptable, only if it is not possible or feasible to perform High Point Calibration.

In summary, the MiniOX III operates satisfactorily within the conditions of the purchase contract and manufacturer's specifications.

Electromagnetic Interference

The monitor passed all EMI tests at all frequencies (Figs. 4 and 5).

Vibration

The MiniOX operated satisfactorily throughout the testing. A visual inspection of the monitor, during and following the testing, revealed everything to be intact and operational. There was no abnormal wear of any of the components. There were occasional incidents of delayed response when the concentration of oxygen was abruptly changed; i.e., from 21%, to 50%, to 100%, and back to 21%. This delayed response was particularly true following sensor shock; due to dropping the sensor to the floor, rapping the sensor on a hard surface, and during the vibration testing. Complete recovery time was usually 30 to 60 min. However, this time was not the norm and the sensor usually adapted, and registered concentration changes within 5 min, an acceptable interval. We also found that the MiniOX must be mounted in a vertical upright position. When mounted in a horizontal position, on its back, the MiniOX tended to slide out of the mounting bracket onto the floor. The manufacturer suggested, and provided the means for, several methods of securing the MiniOX III to the mounting bracket. However, the only acceptable method is using 2 plastic dove-tailed slip-joint devices attached to the back of the unit. Using only the standard 1 slip-

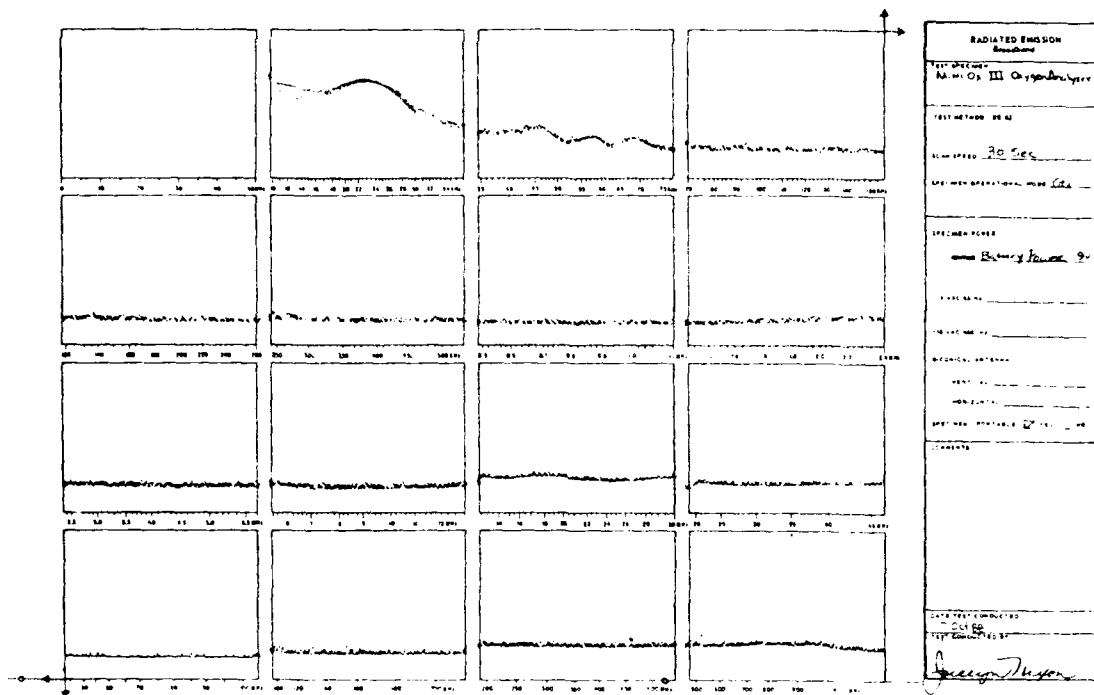


Figure 4. Radiated emission - broadband.

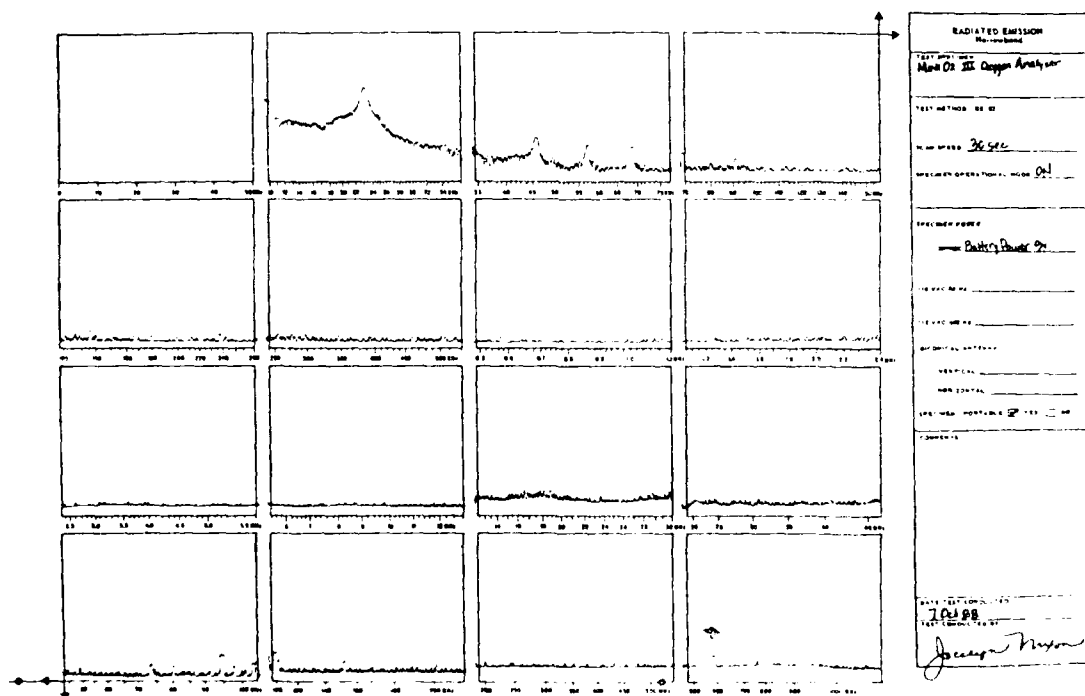


Figure 5. Radiated emission - narrowband.

joint device, the unit does not fit snugly into the corresponding slot on the bracket, and could easily slide out, either inadvertently or due to aircraft vibration.

Environmental

1. Humidity. The MiniOX operated satisfactorily during and after humidity testing. No significant findings.
2. Hot Operation. Initially, following placement in a 48.8 °C (120 °F) environment, with the oxygen percentage abruptly changed from 50 to 100%, the MiniOX reacted in a somewhat sluggish manner. It took 10 min to satisfactorily respond to the change. This change also occurred following the return to room temperature of 24.4 °C (76 °F). On all repeat testing with the same sequence of events, the MiniOX performed satisfactorily.
3. Cold Operation. The MiniOX operated satisfactorily during and after testing. Initially, following placement in a 4.44 °C (40 °F) environment, when the oxygen percentage was changed from 50 to 100%, the MiniOX reacted sluggishly. This action also occurred following testing, and returning the unit to room temperature of 32.2 °C (76 °F). Normally the MiniOX III will respond to the new concentration and stabilize within 3-5 min. However, when a recent temperature change is involved, twice that time may be required.
4. Hot Storage. The MiniOX operated satisfactorily following hot storage. No significant findings.
5. Cold Storage. The MiniOX operated satisfactorily following cold storage. No significant findings. However, according to the manufacturer, the MiniOX III must not be stored in temperatures of 0 °C (32 °F), or below. There is a possibility the potassium hydroxide gel contained within the sensor will freeze, causing the membrane to rupture, if subjected to freezing temperatures. While the sensor, and therefore the MiniOX, will no longer function if this happens, the situation should not be considered hazardous to patients or personnel. The gel remains enclosed within the structure of the sensor.

Altitude

The following reviews the results of testing a single gas concentration, 21%. Measurements of 50 and 100% were also taken, with essentially the same results. Each test within the hypobaric chamber is called a "mission."

1. Three Different Missions, 3 Different Scenarios: The following 3 mission scenarios illustrate the problem of a monitor that senses the partial pressure of oxygen, but expresses it in percentage. The missions explain our test results. The MiniOX was calibrated at sea level (AP of 760 mmHg) before each mission. The chamber then "ascends" to an altitude equivalent of 3,048 m (10,000 ft), AP of 523 mmHg.

a. First Mission: During the first mission, no adjustments were made to the MiniOX or oxygen concentration (constant 21%, room air). Because the MiniOX responds to changes in the oxygen partial pressure, which decreased as atmospheric pressure decreased during ascent, the percent of oxygen displayed on the MiniOX decreased correspondingly. (See the formula below and Fig. 6)

$$\frac{109 \text{ mmHg (PP of 21\% oxygen at 10,000 ft)}}{760 \text{ mmHg (AP at Calibration)}} = 14.3\% \text{ (MiniOX display)} \quad (2)$$

This decrease is due to the fact the MiniOX was calibrated at sea level (760 mmHg), and uses AP to calculate its percentage. While the MiniOX's operation manual states that the analyzer should be calibrated in the environment it will be used, inflight use was clearly not considered, when the manual was written.

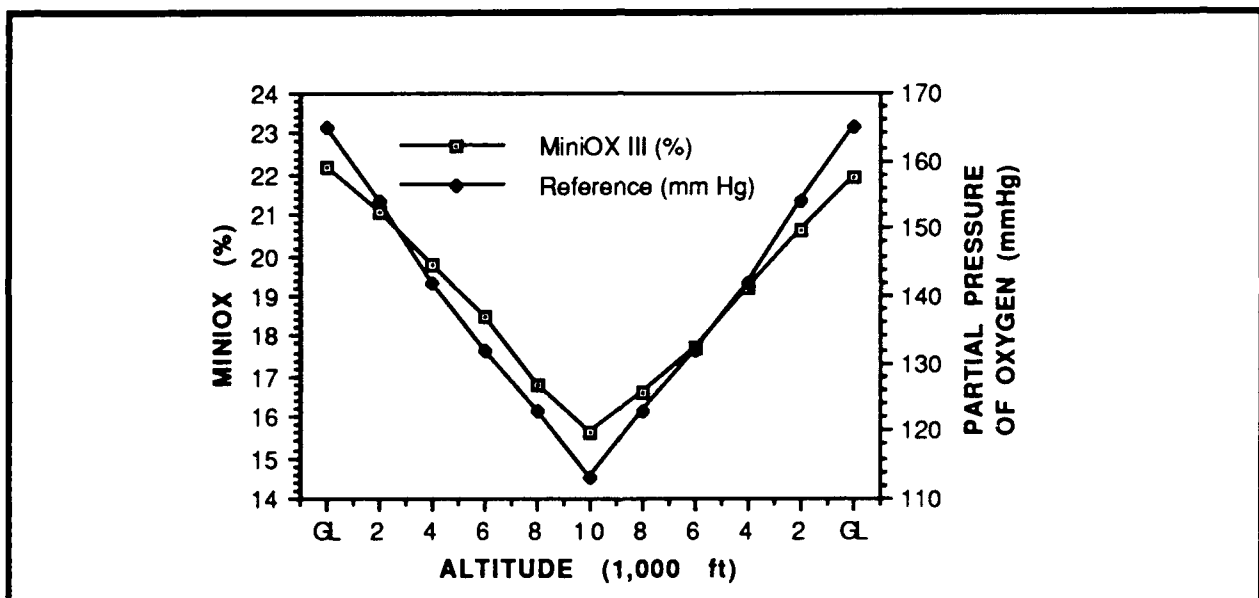


Figure 6. First Mission. No Recalibration or Change in Oxygen Saturation at Altitude.

b. Second Mission: During the second mission, we recalibrated the MiniOX at 609.6 m (2,000 ft) intervals up to 3,048 m (10,000 ft). The oxygen blender was not adjusted during this mission. The percentage of oxygen returned to about 21% (room air). The MiniOX now uses 523 mmHg, the AP at 3,048 m, to calculate percentage. (See formula below and Fig. 7)

$$\frac{109 \text{ mmHg (PP of 21\% at 10,000 ft)}}{523 \text{ mmHg (AP at 10,000 ft)}} = 21\% \text{ (MiniOX display)} \quad (3)$$

As illustrated by Figure 7, when calibrated at room air, regardless of the altitude, the MiniOX read about 21%, even when the partial pressure of oxygen had significantly dropped. If percentage were the clinically significant parameter, recalibrating at cruise altitude would suffice, but since partial pressure of oxygen is what must be maintained, another option is explored.

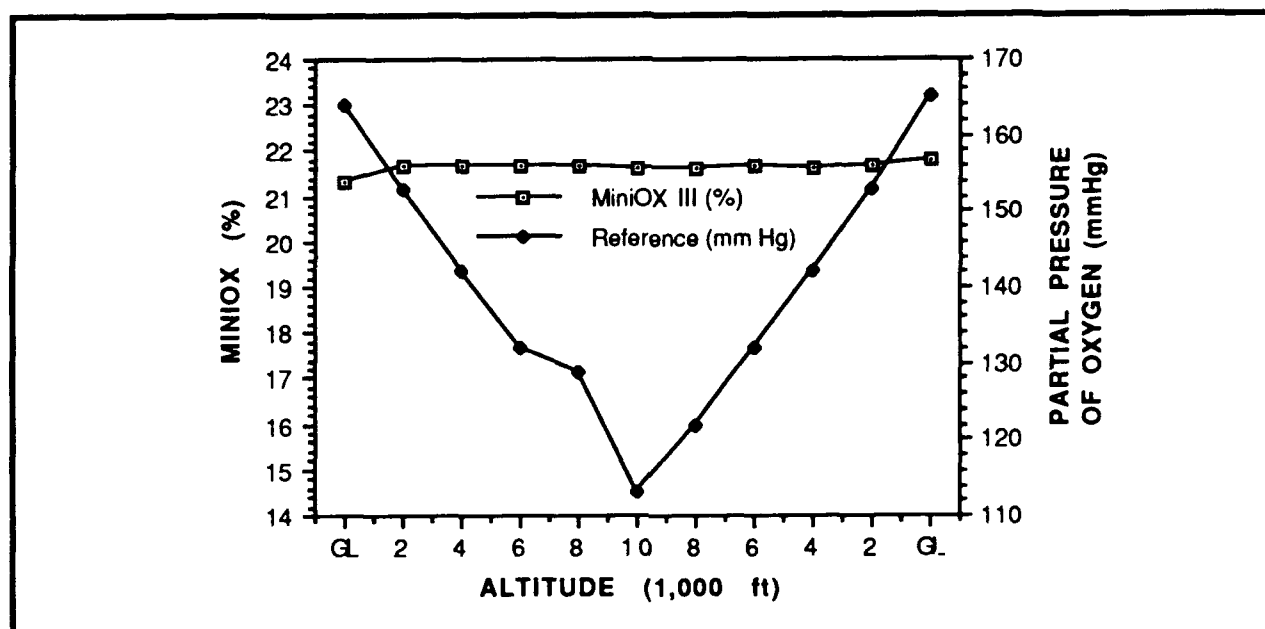


Figure 7. Second Mission. Recalibration at Altitude.

c. Third Mission: No adjustments (calibration or otherwise) were made to the MiniOX during this mission. When reaching 10,000 ft, the MiniOX display had dropped to 14.3%. The blender setting was increased to 30%, resulting in a MiniOX display reading of about 21%. This increase achieved an oxygen partial pressure equivalent to that obtained at ground level (GL). (See the formula below and Fig. 8)

$$0.21 \text{ (MiniOX reading 21\%)} \times 760 \text{ mmHg (AP at GL)} = 160 \text{ mmHg (PP of oxygen at GL)} \quad (4)$$

Recall that the MiniOX uses the AP at the time of calibration to calculate percentage ($PP/AP = \%$). Since no recalibration was done at altitude, the partial pressure and percent reflect those prescribed at ground level. The only difference between this mission and the first mission is that the technician has increased the oxygen concentration, by adjusting the blender setting. Maintaining a constant partial pressure of oxygen ($\% \times AP = PP$), as prescribed by the physician at the originating facility, is paramount.

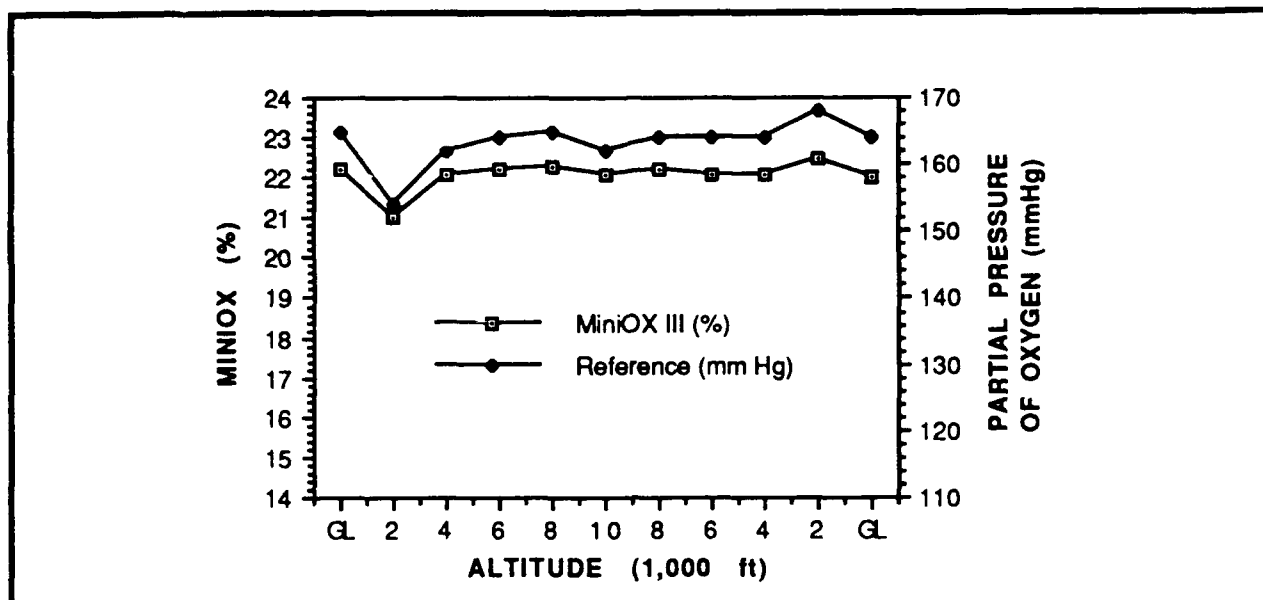


Figure 8. Third Mission. No Recalibration, but Increased Oxygen Saturation at Altitude.

2. Conclusions of Altitude Testing: Based on these tests, the purchase contract specifications (6), and manufacturer's literature, the MiniOX III accurately displays the oxygen percentage at altitudes up to 10,000 ft when calibrated at cruising altitude. However, the clinically relevant parameter is a constant partial pressure of oxygen, as prescribed by the physician at the originating facility ($\% \times AP = PP$). To accomplish this pressure, a modification to the manufacturer's calibration instruction is required. The modification is minor, yet very significant.

3. Modified Normal Calibration Procedure: The modification to the manufacturer's calibration procedure is as follows: After calibrating the unit at the originating facility*, no further calibrations should be accomplished during transport. Normally, according to the manufacturer's literature, the unit would be recalibrated when a change in altitude occurs. Recalibration **would** achieve the correct percentage reading. However, the clinically relevant parameter is a constant partial pressure of oxygen. To **achieve a constant partial pressure of oxygen, DO NOT recalibrate at altitude**. Instead simply adjust the oxygen concentration (flow or blender control) to achieve the same percentage ($\pm 3\%$) prescribed at the originating facility.

Due to the law of physics, higher oxygen concentration levels obtainable at ground level will not be possible at higher altitudes. For example, a ground level equivalent of 75% oxygen cannot be delivered at 8,000 ft. If higher concentrations are required at higher altitudes, the most viable alternatives are to decrease cabin altitude, or to set the oxygen source to maximum flow and hope for the best.

* Calibrating the MiniOx at the originating facility and maintaining the oxygen percentage will give the patients the same partial pressure of oxygen they had been receiving while at that facility, no matter what the equivalent altitude for that location is.

4. Inflight Calibration. Occasionally, calibration may be required during flight for 1 of many reasons, i.e., due to unplanned use inflight, suspected problem with the MiniOX sensor, or required battery replacement. The calibration procedure will remain the same as described in the operating manual, but a conversion chart will be needed to determine the percentage equivalent of the partial pressure prescribed at the originating facility. Referring to the chart in Figure 9, on the bottom line locate the column for desired oxygen percentage, as prescribed by the physician at the originating medical treatment facility. Now, obtain the cabin altitude from the flight crew, and locate the appropriate row on the left side of the table. Now read the value of the oxygen percentage from the table where that row and column meet. Use this percentage for the remainder of the flight. For example, if 50% oxygen was prescribed by the physician at the originating medical treatment facility, and the aircraft altitude is 5,000 ft, following an inflight calibration the oxygen must be modulated to read 60% on the MiniOX, in order to achieve the same partial pressure needed to deliver the 50% achieved at the originating medical treatment facility. **Upon landing, the MiniOX should be calibrated at ground level. At that time, use of the conversion chart will no longer be necessary or appropriate.**

CABIN ALTITUDE (X1,000 FT)	10.0	30	36	44	51	58	65	73	80	87	94	*	*	*	*	*	*
	9.0	29	35	42	49	56	63	70	77	84	91	98	100	100	100	100	100
	8.0	28	34	40	46	54	61	67	74	81	87	93	100	100	100	100	100
	7.0	27	32	39	45	52	58	65	71	78	84	91	97	100	100	100	100
	6.0	26	31	37	44	50	56	62	69	75	81	87	94	100	100	100	100
	5.0	25	30	36	42	48	54	60	66	72	78	84	90	96	100	100	100
	4.0	24	29	35	41	46	52	57	64	70	75	81	87	93	97	100	100
	3.0	23	28	33	39	45	50	56	61	67	73	78	84	89	95	100	100
	2.0	23	27	32	38	43	48	54	59	64	70	75	81	86	91	97	100
	1.0	22	26	31	36	41	47	52	57	62	67	73	78	83	88	93	98
		21	25	30	35	40	45	50	55	60	65	70	75	80	85	90	95
																	100

**DESIRED OXYGEN PERCENTAGE
ESTABLISHED AT GROUND LEVEL**

**CAUTION: DO NOT USE THIS CHART ROUTINELY. USE ONLY WHEN
RECALIBRATION AT ALTITUDE IS WARRANTED.**

*** INDICATES THAT WHILE THE MINIOX III MAY READ 100% THE DESIRED
PARTIAL PRESSURE CANNOT BE ACHIEVED AT THAT ALTITUDE.**

Figure 9. Altitude Post-Calibration Conversion Chart.

5. Rapid Decompression Testing. The MiniOX successfully passed all rapid decompression testing. However, the manufacturer has advised that a rapid decompression could damage the sensor, making the unit inoperable until the sensor is changed.

Airborne Feasibility

The MiniOX performed satisfactorily, according to contract specifications. Indeed it performed as well "in the air" as it did "on the ground". Other specific findings include the following:

1. The MiniOX III "audible" alarms were inaudible in most areas of the C-9A aircraft at distances exceeding 152.4 cm (5 ft). On the C-141B, the alarms were inaudible when the distance exceeded 15.2 cm (6 in.). Therefore the unit should be positioned for optimal visibility of the visual alarms.

2. The MiniOX III easily mounts to the C-9A litter stanchions, but not to those on the C-141B. While not actually checked inflight on the C-130, the MiniOX was evaluated for mounting in the C-130 mockup, located in Building 820 on Brooks AFB. As on the C-141B, mounting on those stanchions could not be satisfactorily accomplished.

3. Possibly due to repeated use, and the decrease in relative humidity, the rubber sensor retaining strap broke.

4. While calibration using room air is acceptable, calibrating using 100% oxygen is a superior method, resulting in a higher degree of accuracy.

5. There was no problem enplaning or deplaning a litter with the MiniOX mounted. However, we recommended that the unit not be mounted on the side of the litter attached to the litter pole, during enplaning and deplaning. Due to the crowded conditions on the aircraft, the unit could be knocked off during the litter movement. We recommend the unit be laid on top of the litter, possibly secured under a litter strap. If an Airborne Infant Life Support Transport Model 185 incubator is being used, the unit could be mounted on the incubator end handles, without protruding, during the litter movement.

6. Several informal inservices and demonstrations were given to a total of about 25 different aeromedical crewmembers. Crewmembers were unanimously pleased with the unit, and are anxiously looking forward to obtaining and using the MiniOX on patients.

REQUIREMENTS AND RECOMMENDATIONS

The following requirements and recommendations were submitted to the office of the 375 Aeromedical Airlift Wing surgeon, in the form of an interim report (7), on 16 March 1989.

1. Requirements:

a. Before use in flight,

(1) The monitor must be calibrated at ground level, using 100% oxygen, at the patient pick-up point.

(2) The desired level of oxygen enrichment ($\pm 2\%$) to the patient must be obtained from the oxygen delivery system, as reflected by the MiniOX III readout. As altitude increases the reading will decrease due to the decrease in the partial pressure of oxygen. The oxygen flow must be increased until the MiniOX III indicates the desired percentage prescribed at the originating medical treatment facility. Actually, by increasing the oxygen flow, the true percentage of oxygen will be raised far above that indicated by the MiniOX III. However, the partial pressure of oxygen, the physiological indicator of oxygen enrichment at altitude, will remain the same as that at ground level. As altitude decreases, the reverse is true.

b. If in-flight calibration is required, following the calibration, a conversion chart must be used to determine the amount of oxygen needed to obtain the same partial pressure (physiological requirement) of oxygen at altitude as that achieved at ground level. While the partial pressure will be the same, the percentage reading on the MiniOX III will be significantly higher. At the next enroute stop, calibration must be reaccomplished. Thereafter, the MiniOX III may be used according to normal in-flight operating procedures, with the original oxygen percentage prescribed by the patient's physician.

c. The manufacturer provided several methods of securing the MiniOX III to the provided mounting bracket. The only method approved is using 2 plastic dove-tailed devices attached to the back of the unit. The dove-tailed devices slip into a corresponding slot on the bracket. It is important that the MiniOX III have 2 of the plastic devices attached. When using the mounting bracket, the MiniOX III must be secured in a vertical position. Mounting horizontally, such as on a NATO litter handle, will result in the monitor falling out of the mounting bracket, due to aircraft vibration.

d. The provided tee-adaptor, used for in-line monitoring of respiratory therapy and for calibration purposes, does not easily attach to the standard, small bore oxygen tubing. To accurately calibrate the MiniOX III using 100% oxygen, a nipple adapter must be provided to fit the standard oxygen tubing.

e. The MiniOX III must not be stored in temperatures of 0°C (32°F) or below. This storage is based on manufacturer's recommendations.

f. The manufacturer's operating manual must be supplemented or modified to include in-flight calibration and operating procedures; also to clarify normal calibration procedures. Suggested additions and changes have been established by the Aeromedical Research Function, and provided to 375 AAW medical logistics personnel.

2. Recommendations:

a. The MiniOX III should be positioned for optimal visibility of the visual alarms. Due to aircraft noise, the "audible" alarms will be inaudible.

b. Additional accessories in the carrying case should include an extra battery, sensor, and sensor retaining strap.

c. The mounting bracket should be secured to the MiniOX III using either thumb screws or Allen screws and a provided Allen wrench. This attachment will facilitate easy repositioning for securing to either a horizontal or a vertical device (such as an intravenous pole).

d. The manufacturer should clarify battery and sensor life expectancy. The operating manual states the battery life to be up to 2,000 h, while other company literature states the battery life to be up to 1,500 h. There is some confusion regarding shelf life and operating life of the sensor. The operating manual states the sensor life to be "1 year in normal medical conditions." Does aeromedical use constitute "normal medical conditions?" If not, can the sensor life be expected to be longer or shorter? The operating manual states the shelf life to be "a minimum of 3 months without degradation of life." Are those 3 months included in the 1 year sensor life?

e. Generally, following sudden temperature changes, the MiniOX III reacts somewhat lethargically to oxygen percentage changes. Users should be aware of this and allow more time for the percentage readings to stabilize, particularly before calibration. Normally, following changes in oxygen concentration, the MiniOX III will respond to the new concentration and will stabilize within 3-5 min. When a recent temperature change is involved, twice that time may be required.

f. Users should be aware that if the sensor sustains shock, such as by dropping against a hard surface, the MiniOX III may temporarily react to changes in oxygen concentration in a somewhat sluggish manner. Usually within 1 h, the unit should return to normal, responding to concentration changes and stabilizing within 3-5 min.

g. Users should be aware that even though the MiniOX III passed the rapid decompression tests, the manufacturer has advised that a rapid decompression could damage the sensor, making the unit inoperable until the sensor is changed.

h. Users should be aware that the sensor securing strap, used to secure the sensor to the tee-adaptor, is made of rubber which, in time, loses its elasticity. The result is that after relatively little use, the strap breaks. Spares should be kept in the accessory case.

CONCLUSIONS

Based upon completed test data, members of the Aeromedical Research Function* have concluded that the MiniOX III Oxygen Monitor is a safe, effective, and reliable instrument for monitoring the concentration of therapeutic oxygen and acceptable for worldwide aeromedical evacuation use.

ACKNOWLEDGMENTS

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Capt Susan Nagel
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MSgt Victor Elizondo
MSgt Gary Jenkins
TSgt R. J. Van Oss

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3. MIL-STD 461C, "Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference," category A1e.
4. USAFSAM Test and Planning Guide for Aeromedical Evacuation Equipment, 1989.
5. MIL-STD-810D, "Environmental Test Methods and Engineering Guidelines," and Supplemental letters AFFDL/FEE, 5 Aug 71 and FEE/D, March 1977.
6. Purchase Contract Specifications.
7. Interim Report to 375 Aeromedical Airlift Wing, 16 March 1989.

* This group comprised flight surgeon, a flight nurse, three biomedical engineers, a medical research technician, a biomedical equipment maintenance technician, and two aeromedical evacuation technicians.

8. Proposed Modified MiniOX III Operators Manual, dated March 1989.
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